



Screening Sheet for Protection of Human Subjects

Organization Name: _____ Vendor Number: _____

Project Title: _____

Application Number [to be completed by BJS]: _____

Please check the appropriate response.

1. Is the project research¹, in whole or in part (including potential subcontracts and evaluation activities)?
☐ Yes - *Continue*
☐ No - *Skip to question 12, check (A)*
2. Does the research project include human subjects²?
☐ Yes - *Continue*
☐ No - *Skip to question 12, check (A)*
3. Does the research project obtain data through intervention³ or interaction⁴ with human subjects or observation of human subjects?
☐ Yes. Data through intervention - *Skip to question 10*
☐ Yes. Data through interaction - *Skip to question 6*
☐ Yes. Data through observation - *Skip to question 6*
☐ No - *Continue*
4. Does this research project use files or records containing information about individual human subjects?
☐ Yes - *Continue*
☐ No - *Skip to question 12, check (A)*
5. Does this research project include identifying information that can link data to individual subjects?
☐ Yes - *Continue*
☐ No - *Skip to question 12, check (A)*
6. Is the research extramural⁵ to the Office of Justice Programs (OJP) or intramural?
☐ Extramural to OJP only - *Continue*
☐ Intramural to OJP only - *Skip to question 9*
☐ Both extramural and intramural to OJP - *Continue*
7. Does your research organization or government agency (other than OJP) have an Institutional Review Board⁶ (IRB)?
☐ Yes - *Continue*
☐ No - *Skip to question 9*

8. Has your IRB been approved by the Office for Protection from Research Risks (OPRR), Department of Health and Human Services (DHHS), or another government agency?
- ☐ OPRR - *Continue*
- ☐ A government agency other than OPRR - *Continue*
- ☐ Not approved by a government agency - *Continue*
9. Does the project include any interactions with human subjects other than survey procedures, interview procedures, or observations of public behavior?
- ☐ Yes - *Continue*
- ☐ No - *Skip to question 12. Check (B)*
10. Does the research involve children⁷, prisoners⁸, pregnant women, or fetuses?
- ☐ Yes - *If question 8 is marked "yes," skip to question 12 and check (E). Else continue*
- ☐ No - *Continue*
11. Does this research project involve more than minimal risk⁹ to human subjects?
- ☐ Yes - *Skip to question 12. Check (D)*
- ☐ No - *Skip to question 12. Check (C)*
12. Determination. *Check only one*
- ☐ A. No further review regarding human subjects is required. There are no living human subjects involved or the study poses little or no risk to any subjects.
- ☐ B. Research probably qualifies for an exemption.
- ☐ C. Research should undergo an expedited review by an IRB. The risk of harm to human subjects is minimal.
- ☐ D. Research should undergo a full IRB review. The risk to human subjects is more than minimal.
- ☐ E. Research should undergo a full IRB review. Human subjects are involved in the research and it involves a special population. Subparts B,C, and D of 45 CFR Part 46 apply.

Funding Recipient:

Signature of Person Authorized to Sign

Date

Name and Title of Person Authorized to Sign

U.S. Department of Justice, Bureau of Justice Statistics:

Signature of BJS Representative

Date

Endnotes: BJS Screening Sheet for Protection of Human Subjects

¹ Research is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 28 CFR 46.102(d)

² Human subject means a living individual about whom a researcher obtains information. 28 CFR 46.102(f)

³ Intervention includes both physical procedures and manipulations of the subject or the subject’s environment for research purposes. 46 CFR 46.102(f)

⁴ Interaction includes communication or interpersonal contact with the subject. 28 CFR 46.102(f)

⁵ Extramural research is any research funded or supported by the Office of Justice Programs (OJP) under grants, contracts, interagency agreements, or cooperative agreements. Intramural research is research conducted by OJP employees or contract staff. BJS projects may fit both definitions; they are funded by grants, contracts, interagency agreements, or cooperative agreements and BJS staff are also involved. See OJP Instruction, “Protection of Human Subjects of Research and Statistical Activities,” April 26, 1999

⁶ An Institutional Review Board (IRB) is an organization of at least 5 members, representing a variety of backgrounds, which reviews and approves research and statistical activities involving human subjects. Before an IRB can review and approve U.S. government-funded research, it must have been approved by a U.S. government agency, for example, the Director, BJS, or the Office for Protection from Research Risks (OPRR), DHHS. The approval is based upon review of documentation assuring that the IRB will comply with the Common Rule and describing its organization. See in particular 28 CFR sections 46.103, 46.107, and 46.108.

⁷ Children are persons who have not attained the legal age for consent under applicable law of the jurisdiction in which the research will be conducted. 45 CFR 46.402(a)

⁸ Prisoners include those confined or detained in a correctional facility or in a program alternative to prosecution or incarceration. 45 CFR 46.303(c)

⁹ Minimal risk means that the probability and magnitude of harm or discomfort anticipated are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 28 CFR 46.102(i)